

REMARKS/ARGUMENTS

Claims 2-8 are active.

Claim 2 replaces original Claim 1 and defines the method by measuring antibody titer with an antibody directed against a peptide consisting of SEQ ID NO:1. Support for this claim is found in original claim 1 as well as throughout the specification as originally filed (see e.g., page 10).

Claims 3-8 are supported by the disclosure on page 12.

No new matter is added by the presentation of these claims.

It is noted that the present application is related to U.S. application serial no. 10/714,852.

The rejection under 35 USC 112, second paragraph is no longer applicable as claim 1 has been cancelled.

The rejection based on Matsushita is respectfully traversed.

Matsushita studies and discusses certain reactive epitopes of Pac that could be used for diagnostic tests (see page 4040, 2nd column, last paragraph). Matsushita discusses these studies as a first step in the development either of specific diagnostic tests or of a vaccine against human dental caries, but did not disclose examining caries risk by measuring the antibody titer of the secretory immunoglobulin A (sIgA). Moreover, there is nothing in Matsushita which discusses examining caries risk with an antibody directed against a peptide consisting of SEQ ID NO:1 as set forth in Claim 2 nor correlating the titer of the antibody in the human saliva to caries risk.

Accordingly, withdrawal of this rejection is requested.

- Application No. 10/658,544
- Reply to Office Action of September 21, 2006

The rejection that the claimed method as not enabled is also traversed. In particular, the Examiner states that the method of using SEQ ID NO:1 is not actually predicated of dental caries because determining a single time point of reactivity does not correlate with caries risk, also referencing the discussion in the Matsushita publication as well (see the paragraph bridging pages 2-3 of the Official Action). Applicants disagree and for the reasons discussed below, submit that the claimed method is enabled.

First, it should be noted that claim 2 includes the manner in which caries risk is assessed the relationship between the titer and caries risk as discussed throughout the specification (including the Examples).

As discussed on pages 5-6 of the specification there has been some recent studies that observed the presence of Pac on the surface of mutans streptococci and this was related to the initial adhesion of the mutans streptococci to the tooth surface. Therefore, if a person whose antibody titer against the antigen is high, there would be an indication that streptococci inhibition would be occurring meaning a lower relative risk of caries in that individual. However, it was subsequently found that the level of infection and the caries risk could not be adequately correlated. This was perhaps due in part to the presence of a human immunoglobulin directed against an array of antigens on the surface of the mutans streptococci.

What the inventors found is that if they utilized a synthetic peptide having only the sequence in the region of 361-386 (denominated as SEQ ID NO:1 in this application), then the caries risk can be accurately examined in short time based on the initial adhesion of the mutans streptococci to the tooth surface. Indeed, the Examples presented in the specification show that this correlation exists.

Table 1 on page 20, shows antibody titers in saliva of five subjects (A, B, C, D, E) measured by ELISA assays. In this data set, the quantity of the mutans streptococci in saliva of subjects A, C, E in which antibody titers are high (high titer indicates an inhibition of the mutans streptococci at the tooth surface and therefore lower quantity of the streptococci) and as such the caries risk is relatively low. In contrast, in subjects B and D, the antibody titers are low meaning higher quantities of the streptococci and therefore higher relative risk of caries in those subjects.) of which antibody titers are low (low inhibits of the mutans streptococci to the tooth surface).

In Table 2 on page 23, antibody titers were measured by Immuno-Chromatography. The data set presented here shows similar results to those in Table 1. Notably, the higher quantities of streptococci is indicative of a higher relative risk of caries.

Therefore, the data coupled with the description provided in the specification provides a reasonable correlation between antibody titers, streptococci quantities and relative risks of caries.

Withdrawal of this rejection is requested.

Allowance of the claims is requested.

Respectfully submitted,

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